Application No.: 10/517,453

Docket No.: 4705-0106PUS1

Docket No.: 4705-0106PUS1

(PATENT)

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of: Ogari PACHECO et al.

Application No.: 10/517,453

Filed: December 9, 2004

For: SOLUBLE STABLE PHARMACEUTICAL

COMPOSITION FOR THE

ADMINISTRATION OF HIV PROTEASE INHIBITORS AND A PROCESS FOR THE PREPARATION OF CONCENTRATED PHARMACEUTICAL COMPOSITIONS FOR THE ADMINISTRATION OF HIV PROTEASE

**INHIBITORS** 

Confirmation No.: 5587

Art Unit: 1615

Examiner: Not Yet Assigned

## INFORMATION DISCLOSURE STATEMENT (SUBMISSION AFTER FILING OF AN APPLICATION BUT BEFORE FINAL REJECTION OR NOTICE OF ALLOWANCE OR CONCURRENTLY WITH A RULE 1.114 RCE APPLICATION)

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Pursuant to 37 C.F.R. §§ 1.97 and 1.98, applicant(s) hereby submit(s) an Information Disclosure Statement for consideration by the Examiner.

## I. LIST OF PATENTS, PUBLICATIONS OR OTHER INFORMATION

The patents, publications, or other information submitted for consideration by the Office are listed on the PTO-SB08(s), attached hereto.

Application No.: 10/517,453 Docket No.: 4705-0106PUS1

## II. <u>COPIES</u>

language is as follows:

$\boxtimes$	a.	Copies of cited U.S. patents and patent application publications are not included.			
Copie	s of fore	eign patent documents and non-patent literature are included.			
	b.	Some or all of the documents listed on the PTO-SB08 are not enclosed because			
they v	vere cite	ed in the International Search Report and copies should already be in the PTO file.			
If cop	ies are n	eeded, please contact the undersigned.			
	c.	REFERENCES PREVIOUSLY CITED OR SUBMITTED - Pursuant to 37 C.F.R.			
§1.98	(d), con	sideration of information listed on the PTO-SB08 form(s) is requested since any			
patent	s, publi	cations, or other information which are listed on the PTO-SB08 form(s) but for			
which	copies	are not enclosed herewith, were previously cited by or submitted to the PTO in one			
of the	follow	ing applications which has been relied upon for an earlier filing date under 35			
U.S.C	. § 120:				
	•				
	<u>U.</u>	S. Appl. No(s) and U.S. Filing Date			
		filed			
		med .			
III.	CONC	SISE EXPLANATION OF THE RELEVANCE			
	(check at least one box)				
$\boxtimes$	a.	DOCUMENTS IN THE ENGLISH LANGUAGE - The patents, publications, or other			
inform	nation li	sted on the attached PTO SB08 are in the English language and therefore, do not			
requir	e a state	ment of relevancy.			
	b.	DOCUMENTS NOT IN THE ENGLISH LANGUAGE - A concise explanation of the			

relevance of all patents, publications, or other information listed that is not in the English

ENGLISH LANGUAGE SEARCH REPORT - An English language version of the search C. report or action that indicates the degree of relevance found by the foreign office is attached, thereby satisfying the requirement for a concise explanation. See MPEP 609(III)(A)(3). d. OTHER - The following additional information is provided for the Examiner's consideration. IV. <u>FEES</u> (check one box) This Information Disclosure Statement is being filed concurrently with the filing of a new patent application; therefore, no fee is required. b. This Information Disclosure Statement is being filed concurrent with the filing of a continuation-in-part, continuation, or divisional patent application; therefore, no fee is required. This Information Disclosure Statement is being filed within three months of the filing date of a national application (37 C.F.R. § 1.97(b)(1)). No fee or statement is required. (This section is not to be used with RCE's.) d. This Information Disclosure Statement is being filed within three months of the date of entry of the national stage as set forth in § 1.491 in an international application (37 C.F.R.  $\S 1.97(b)(2)$ ). No fee or statement is required. e. This Information Disclosure Statement is being filed concurrently with the filing of a Request for Continued Examination under § 1.114 (37 C.F.R. § 1.97(b)(4)). No fee or statement is required. X f. This Information Disclosure Statement is being filed before the mailing date of a first Action on the merits (37 C.F.R. § 1.97(b)(3)). No fee or statement is required. In the event that a first Office Action on the merits has been issued, please consider this IDS under 37 C.F.R. § 1.97(c) and see the statement under 37 C.F.R. § 1.97(e) below, or, if no statement has been made, charge our deposit account for the fee as required by 37 C.F.R. § 1.17(p).

3

Docket No.: 4705-0106PUS1

DRN/mua

Application No.: 10/517,453

Application No.: 10/517,453 Docket No.: 4705-0106PUS1 This Information Disclosure Statement is being filed before the mailing date of a Final Office Action under 37 C.F.R. § 1.113 (See 37 C.F.R. § 1.97(c)(1)) or before the mailing date of a Notice of Allowance under 37 C.F.R. § 1.311 (See 37 C.F.R. § 1.97(c)(2)). No statement; therefore, a fee as required by 37 C.F.R. § 1.17(p) is attached. or See the statement below. No fee is required. V. STATEMENT UNDER 37 C.F.R. § 1.97(e) (check only one box) The undersigned hereby states that: Each item of information contained in the IDS was first cited in any a. communication from a foreign Patent Office in a counterpart foreign application not more than 30 days prior to the filing of this IDS; or b. Each item of information contained in the IDS was first cited in any communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS; or No item of information contained in the IDS was cited in a communication from a c. foreign Patent Office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of IDS was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of the IDS. d. Some of the items of information were cited in a communication from a foreign Patent Office. As to this information, the undersigned states that each item of information contained in the IDS was first cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS. As to

Application No.: 10/517,453 Docket No.: 4705-0106PUS1

the remaining information, the undersigned hereby states that no item of this remaining information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application and, to the best of my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this statement.

VI.	PAYMENT OF FEES	(check one box)
-----	-----------------	-----------------

	The required fee is listed on the attached Fee Transmittal.
$\boxtimes$	No fee is required.

If the Examiner has any questions concerning this IDS, he/she is requested to contact the undersigned. If it is determined that this IDS has been filed under the wrong rule, the PTO is requested to consider this IDS under the proper rule and charge the appropriate fee to Deposit Account No. 02-2448.

Application No.: 10/517,453 Docket No.: 4705-0106PUS1

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

Dated: October 14, 2005

Respectfully submitted,

Mark J. Nuell, Ph.D. Registration No.: 36,623

BIRCH, STEWART, KOLASCH & BIRCH, LLP

8110 Gatehouse Rd Suite 100 East

P.O. Box 747

Falls Church, Virginia 22040-0747

(703) 205-8000

Attorney for Applicant

Attachment(s):

$\boxtimes$	PTO-SB08
$\boxtimes$	Documents
	Foreign Search Report
	Fee
П	Other:



PTO/SB/08a/b (07-05) Approved for use through 07/31/2006. OMB 0651-0031 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Sub	estitute for form 1449A/B/PT	0	·	Complete if Known	
				Application Number	10/517,453-Conf. #5587
l IN	<b>NFORMATION</b>	I DI	SCLOSURE	Filing Date	December 9, 2004
S	TATEMENT I	3Y /	APPLICANT	First Named Inventor	Ogari PACHECO
				Art Unit	1615
	(Use as many sh	eets as	s necessary)	Examiner Name	Not Yet Assigned
Sheet	1	of	1	Attorney Docket Number	4705-0106PUS1

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No.1	Document Number  Number-Kind Code <sup>2</sup> ( <i>if known</i> )	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	

FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No.1	Foreign Patent Document  Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (# known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T⁵	
	BA	WO-98/57648-A1	12-23-1998				

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at <a href="https://www.uspto.gov">www.uspto.gov</a> or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁰ Applicant is to place a check mark here if English language Translation is attached.

	NON PATENT LITERATURE DOCUMENTS					
Examiner Initials	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>			
	CA	L. ELDRED, The Hopkins HIV Report, "Adherence in the Era of Protease Inhibitors", 1997.				
	СВ	F.M. HECHT et al., Abstract of Presentation from the 5th Conference on Retroviruses and Opportunistic Infections, February 1-5, 1998, Chicago, IL.				
	СС	M. CHESNEY et al., "Adherence to Combination Therapy in AIDS Clinical Trials (1997)", presented at the Annual Meeting of the AIDS Clinical Trials Group, July 1997, Washington, D.C.				
	CD	J. WALSH et al., Abstract of presentation "Adherence to proteinase inhibitor based highly effective antiretroviral therapy (HEART)" from 12th International AIDS Conference held in Geneva, Switzerland, June 28-July 3, 1998.				

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Examiner	Date
Signature	Considered

Birch, Stewart, Kofasch & Birch, LLP

<sup>&</sup>lt;sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.